

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Khan et al.

Serial No.: 09/821,380

Filed: March 29, 2001

For: IMMUNOREGULATOR

Confirmation No.: 3457

Examiner: J. Witz

Group Art Unit: 1651

Attorney Docket No.: 2183-4799US

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

| <u>U.S. Patent No.</u> | <u>Publication Date</u> | <u>Patentee</u> |
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| #US- 4,977,244 | 12-11-1990 | Muchmore et al. |
| #US- 5,677,275 | 10-14-1997 | Lunardi-Iskandar et al. |
| #US- 5,877,148 | 03-02-1999 | Lunardi-Iskandar et al. |

Serial No.: 10/409,027

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| #US- 5,968,513 | 10-19-1999 | Gallo et al. |
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| #US- 6,583,109 B1 | 06-24-2003 | Gallo et al. |
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| #US- 2002/0064501 | 05-30-2002 | Khan et al. |
| #US- 2002/0041871 | 04-11-2002 | Brudnak |
| #US-5,851,997 | 12-22-1998 | Harris |
| #US- 6,489,296 | 12-03-2002 | Grinnell et al. |

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| <u>Document No.</u> | <u>Publication Date</u> | <u>Patentee</u> |
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| #EP 1 300 418 | 04-09-2003 | Erasmus Universiteit Rotterdam |
| #WO 98/35691 | 08-20-1998 | Proscript, Inc. |
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| #DE 3715662 | 11-19-1987 | The Wellcome Foundation Ltd. |
| #DE 19953339 | 05-17-2001 | Goldham Pharma GmbH |
| #96/04008 | 02-15-1996 | Government of the United States |
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University of Maryland
Biotechnology Institute

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#JYONOUCHI et al., Proinflammatory and regulatory cytokine production associated with innate and adaptive immune responses in children with autism spectrum disorders and developmental regression, *J Neuroim.*, 2001, pp. 170-79, Vol. 120.

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#PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 *ACTA NEUROCHIR (WIEN)* 76-78 (1987).

#ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on *Plasmodium falciparum* in vitro, *Zentralblatt Bakt*, 1999, pp. 89-99, Vol. 289.

#SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin, "23(1) *TRANSPLANTATION* 103-104 (January 1977).

#TAK et al., NF-kappaB: a key role in inflammatory diseases, *J Clin Invest.*, 2001, pp. 7-11, Vol. 107.

#TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, *Acta Physiol Sinica*, 2003, pp. 58-64, Vol. 55.

#TOVEY et al., Mucosal Cytokine Therapy: Marked Antiviral and Antitumor Activity, *J. Interferon Cytokine Res.*, 1999, pp. 911-21, Vol. 19.

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#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997).

#KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells *in Vitro*," 20(5-6) PLACENTA, page A37 (July 1999).

#KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) HUMAN IMMUNOLOGY 1315-1323 (December 2001).

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#MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.

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Serial No.: 09/716,777

Filed: November 20, 2000

For: IMMUNOREGULATOR, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

Serial No.: 10/409,027

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 3077-4618.1US
Serial No.: 10/678,995
Filing Date: 10/3/2003
Title: IMMUNOREGULATOR

Attorney Docket No.: 3077-6084US
Serial No.: 10/753,510
Filing Date: 1/7/2004
Title: IMMUNOREGULATORY COMPOSITIONS

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of the first Office Action on the merits subsequent to the filing of an RCE in the above-identified application.

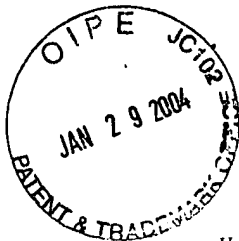
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Date: January 26, 2004
ACT/bv
Enclosures: Form PTO/SB/08

Document in ProLaw



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

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| | | Application Number | To be assigned | | |
| | | Filing Date | January 7, 2004 | | |
| | | First Named Inventor | Khan et. al. | | |
| | | Group Art Unit | 1632 (presumed) | | |
| | | Examiner Name | T. McKelvey (presumed) | | |
| Sheet | 1 | of | 4 | Attorney Docket Number | 3077-5951US |

| U.S. PATENT DOCUMENTS | | | | | |
|------------------------|--------------------------|--|--------------------------------|--|---|
| Examiner Initials * | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number - Kind Code ² (if known) | | | |
| | | #US- 4,977,244 | 12-11-1990 | Muchmore et al. | |
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| | | #US- 2002/0064501 | 05-30-2002 | Khan et al. | |
| | | #US- 2002/0041871 | 04-11-2002 | Brudnak | |
| | | #US- 5,851,997 | 12-22-1998 | Harris | |
| | | #US- 6,489,296 | 12-03-2002 | Grinnell et al. | |
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| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | | #EP 1 138 692 A1 | 10/04/2001 | Erasmus Universiteit Rotterdam | | |

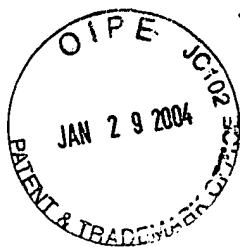
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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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| | | Application Number | To be assigned |
| | | Filing Date | January 7, 2004 |
| | | First Named Inventor | Khan et. al. |
| | | Group Art Unit | 1632 (presumed) |
| | | Examiner Name | T. McKelvey (presumed) |
| Sheet 2 of 4 | Attorney Docket Number | 3077-5951US | |

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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| Examiner Name | T. McKelvey (presumed) |
| Attorney Docket Number | 3077-5951US |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

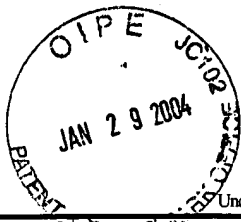
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| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | |
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| | | #ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 CLINICAL & EXPERIMENTAL METASTASIS 739 (1999). | |
| | | #BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997). | |
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| | | #MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160. | |
| | | #WULCZYN, F. Gregory, et al., "The NF-kB/Rel and I κ B gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996). | |
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